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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,201	09/25/2001	Steven J. Brown	AXIOM.016A	2903

7590 06/28/2004

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EXAMINER

GARVEY, TARA L

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,201

Applicant(s)

BROWN ET AL.

Examiner

Tara L Garvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 8, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42, drawn to methods for identifying ion channel modulators and membrane receptor modulators, classified in class 435, subclasses 325 and 6.
- II. Claim 43, drawn to the sequence of an inducible vector containing an ion channel target, classified in class 435, subclass 320.1.
- III. Claims 44, 46 and 47, drawn to inducible expression vector and cells containing the vector, classified in class 435, subclass 320.1 and 325.
- IV. Claim 45, drawn to inducible regulatory expression vector, classified in class 435, subclass 320.1.
- V. Claim 48, drawn to an ion channel modulator molecule, classified in class 530, subclass 350.
- VI. Claims 49 and 50, drawn to a membrane receptor molecule, classified in class 530, subclass 350.
- VII. Claims 51 and 52, drawn to a kit containing cells that conditionally express an ion channel target and a fluorescent dye, an inducer and an indicator compound for ion channel activity, classified in class 435, subclass 325.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: Group I is comprised multiple inventions drawn to a method of identifying a type of target (i.e. ion channel target) reading on claims 14, 15, etc. and method to identifying a type of membrane receptor reading on claims 25, 26, etc. that are chemically, and functionally distinct, and don't render the other obvious set forth in claim 1. If Group I is elected, applicants must elect a single invention which is drawn to either a type of target or a type of membrane receptor to which the claims will be restricted.

This application contains claims directed to the following patentably distinct species of the claimed invention: method of promoter induction. If Group I is elected, then the species applies and applicants must elect either removal or inhibition of a repressor as method of promoter induction. For example, choose one from claim 8.

This application contains claims directed to the following patentably distinct species of the claimed invention: different inducible promoters. If Group I is elected, then the species applies and applicants must elect an inducible promoter. For example, choose one from claim 20.

This application contains claims directed to the following patentably distinct species of the claimed invention: different ion channels. If Group I is elected, then the

species applies and applicants must elect an ion channel. For example, choose one from claim 22.

This application contains claims directed to the following patentably distinct species of the claimed invention: different receptor targets. If Group I is elected, then the species applies and applicants must elect a receptor target within the context of a membrane receptor. Applicant must indicate if the elected receptor target reads on claims 41 and 42. For example, choose one from claim 32.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Groups II-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different effects, i.e. methods of identifying molecules (Group I) versus products such as DNA vector sequences, cells transfected with DNA vector, ion channel modulator molecules, membrane receptors, and a kit containing cells expressing a DNA vector, inducer and an indicator molecule (Groups II –VII).

The nucleic acid sequence of Group II, inducible vector and cells containing the vector of Group III, regulatory expression vector of Group IV, the ion channel modulator of Group V, the membrane receptor of Group VI and the kit containing cells, an inducer and an indicator compound of Group VII are chemically, biologically, and functionally distinct from each other and thus one group does not render the other obvious. The product of each group is not needed to produce the products of the other groups. Therefore, the inventions of the groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions

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daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
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TLG



**JAMES KETTER
PRIMARY EXAMINER**